IN THE UNITED STATES DESIGNATED OFFICE (DO/US)

In re: Jeffrey Alan Warden, et al. Attn: DO/US
Application Serial No. To be assigned
International Filing Date: October 26, 2004
For: **DRY POWDER DRUG CONTAINMENT SYSTEM PACKAGES WITH TABS, INHALERS AND ASSOCIATED METHODS**

Date: April 21, 2006

Mail Stop PCT
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

PRELIMINARY AMENDMENT

Sir:

Prior to the examination of the above application, please amend the above-identified application as follows. If any extension of time for the accompanying response or submission is required, Applicant requests that this be considered a petition therefor. The Commissioner is hereby authorized to charge any additional fee, which may be required, or credit any refund, to Deposit Account No. 50-0220.

Amendments to the Specification begin on page 2 of this document.

Amendments to the Claims are reflected in the listing of claims, which begins on page 3 of this document.

Remarks begin on page 13 of this document.

Amendments to the Specification:

Please replace the paragraph at page 1, line 5, with the following amended paragraph.

This application is a national stage application of PCT/US2004/035424, filed October 26, 2004, which claims priority to U.S. Provisional Application Serial No. 60/514,733, filed October 27, 2003 and U.S. Provisional Application Serial No. 60/605,484, filed August 30, 2004, the contents of the above applications are hereby incorporated by reference as if recited in full herein.

This listing of the claims replaces all prior versions in the application.

Listing of Claims:

1. (Original) A multi-dose drug containment system package adapted for use in an inhaler, comprising:

a support member comprising a plurality of spaced apart drug compartments, each drug compartment having a sealant material detachably sealed thereto; and

a plurality of spaced apart tab members, a respective tab member attached to a portion of sealant material that extends over one or more drug compartments, wherein a respective tab member is operatively associated with at least one drug compartment so that, in operation, the respective tab member is configured to be grasped, such grasping causing the associated sealant material to pull away from at least one drug compartment to release a drug held therein.

2. (Original) A drug containment system according to Claim 1, further comprising a meted dose of dry powder disposed in each drug compartment.

3. (Original) A drug containment system according to Claim 1, wherein the tab members comprise loop members disposed proximate an outermost edge portion of the support member.

4. (Original) A drug containment system according to Claim 3, wherein the support member is generally shaped as a card and/or disc and has a generally rigid elastomeric body.

5. (Original) A drug containment system according to Claim 1, wherein the tab member has increased structural rigidity relative to the sealant material.

6. (Original) A drug containment system according to Claim 3, wherein the loop member is configured with a closed perimeter about an aperture.

7. (Original) A drug containment system according to Claim 1, wherein the tab member comprises an elastomeric material.

8. (Original) A drug containment system according to Claim 3, wherein the loop members extend generally downwardly in position in an inhaler.

9. (Original) A drug containment system according to Claim 7, wherein the sealant material comprises foil, and wherein the tab member has increased structural rigidity relative to the sealant material and less structural rigidity than the support member.

10. A drug containment system according to Claim 1, wherein a respective tab member is operatively associated with a plurality of drug compartments.

11. (Original) A drug containment system according to Claim 10, wherein each tab member is operatively associated with a first and second drug compartment, each drug compartment holding a different meted drug.

12. (Original) A drug containment system according to Claim 1, wherein the support member is a unitary generally rigid elastomeric body with opposing upper and lower primary surfaces and a plurality of cavities formed therein, the cavities being open at the lower primary surface and defining the drug compartments.

13. (Original) A drug containment system according to Claim 12, wherein the upper primary surface of the support member defines a closed generally planar ceiling over all of the cavities.

14. (Original) A drug containment system according to Claim 13, wherein the sealant material of each drug compartment is attached to the lower primary surface of the support member, and wherein the tab members are disposed at an outermost edge portion of the lower primary surface of the support member and extend away from the lower primary surface thereof in a generally downward direction in position in an inhaler.

15. (Original) A drug containment system according to Claim 14, wherein the sealant material is a unitary layer that extends across the lower primary surface of the support member and includes preferentially weakened release regions in communication with each tab member, the regions spanning selected neighboring pairs of drug compartments.

16. (Original) A drug containment system according to Claim 14, wherein the sealant material is configured as a plurality of sealant material strips, one of each of which is associated with a respective tab member.

17. (Original) A drug containment system according to Claim 16, wherein each strip extends across a plurality of neighboring spaced apart drug compartments and, in operation, is configured to expose the neighboring plurality of drug compartments for generally concurrent release.

18. (Original) A drug containment system according to Claim 1, wherein each tab member is operatively associated with at least two neighboring drug compartments, and wherein the neighboring drug compartments each hold a meted amount of a different dry powder drug to thereby allow combination inhalation dry powder drug delivery in operative position in an inhaler.

19. (Original) A drug containment system according to Claim 1, wherein the plurality of drug compartments is at least 60.

20. (Original) A drug containment system according to Claim 19, wherein the plurality of drug compartments is between about 90 to about 120.

21. (Original) A drug containment system according to Claim 3, wherein the loop members extend generally horizontally in operative position in an inhaler.

22. (Original) A drug containment system according to Claim 19, wherein the support member has a generally circular profile, and wherein the plurality of drug compartments comprise a first plurality of circumferentially spaced apart drug compartments disposed about a substantially common first radius extending from a center of the support member and a second plurality of circumferentially spaced apart drug compartments disposed about a second substantially common longer radius extending from the center.

23. (Original) A drug containment system according to Claim 22, wherein each tab member is operatively associated with one drug compartment disposed in the first radius location and one second drug compartment disposed in the second radius location.

24. (Original) A drug containment system according to Claim 19, wherein the support member has a width and length that is about 4.5 inches or less.

25. (Original) A drug containment system according to Claim 12, wherein the support member drug compartment cavities have a thickness that is less than about 0.25 inches, and wherein the drug containment system is disposable after the drug or drugs therein have been dispensed in an inhaler.

26. (Original) A dry powder inhaler comprising:

an elongate chamber having opposing first and second end portions, a floor, and a ceiling with dry powder entry window, the first end portion merging into an inhaler mouth port and the second end portion merging into an air inlet port such that the mouth and air inlet ports are in fluid communication;

a vibrator operatively associated with a portion of the elongate chamber; and

a multi-dose dry powder package comprising a plurality of spaced apart discrete meted amounts of particulate dry powder in respective sealed drug compartments, wherein, in operation, at least one of the compartments is configured to align with the chamber entry window to release at least one meted amount of dry powder therein.

Claims 27-36 (Canceled).

37. (Original) A dry powder inhaler according to Claim 26, wherein the drug compartments comprise a detachable sealant material, the inhaler further comprising a translating hook member held in the inhaler, wherein, in operation, the hook member is operatively associated with one or more drug compartments as the dry powder package rotates the drug compartments into an active dispensing position in the inhaler, the hook member configured to engage and peel the sealant material off the one or more drug compartments held in the active dispensing location and release the dry powder held therein into the window of the elongate channel.

38. (Original) A dry powder inhaler according to Claim 37, wherein, in operative position, the hook member is held generally horizontally below at least one dry powder package compartment proximate the elongate channel window.

39. (Original) A dry powder package according to Claim 38, wherein the hook member is configured with an elongate primary portion that merges into a curvilinear

secondary portion that is disposed above the primary portion, the secondary portion having a forward edge portion thereof that faces the direction of the mouth port.

40. (Original) A dry powder inhaler according to Claim 37, wherein, in operation, the hook member translates in the inhaler toward the mouth port to pull the detachable sealant material off one or more target drug powder compartments.

41. (Original) A dry powder inhaler according to Claim 37, wherein, after removal from a respective drug compartment by the hook member, the sealant material remains attached to the dry powder package such that the respective at least one drug compartment has a lowermost portion that is open to allow the dry powder to fall through the window unimpeded by the sealant material.

42. (Original) A dry powder inhaler according to Claim 37, wherein the hook member curvilinear portion is disposed closer to the air inlet port than the mouth port.

43. (Original) A dry powder inhaler according to Claim 26, wherein each drug compartment comprises a floor comprising a detachable sealant material, and wherein the dry powder package further comprises a plurality of generally downwardly extending tab members attached to selected portions of the floor sealant material proximate one or more drug compartments.

44. (Original) A dry powder inhaler according to Claim 43, wherein the tab members are circumferentially spaced apart and attached about an outermost edge portion of the dry powder package.

45. (Original) A dry powder inhaler according to Claim 43, wherein the tab members are configured as loop members.

46. (Original) A dry powder inhaler according to Claim 43, wherein the tab members are configured with a closed loop perimeter surrounding an aperture.

47. (Original) A dry powder inhaler according to Claim 26, further comprising a moveable mouthpiece cover that is rotatable to expose the mouth port and the air inlet port.

48. (Original) A dry powder inhaler according to Claim 47, wherein the mouthpiece cover is pivotally attached to the inhaler and is configured to rotate to concurrently expose both the mouth port and the air inlet port during operative use, then rotate to concurrently cover both the mouth port and the air inlet port during non-use.

Claims 49-50 (Canceled).

51. (Original) A multi-dose dry powder inhaler, comprising:

an inhaler having a housing body with a mouthpiece port and a spaced apart air inlet port disposed upstream thereof;

a multi-dose dry powder package held in the inhaler, the package comprising a plurality of spaced apart drug compartments with a meted amount of dry powder drug held therein, each compartment operatively associated with a tab member, held in the inhaler; and

a hook member disposed in the inhaler to translate between forward and rearward positions to engage a target tab member and pull thereon, thereby selectively pulling the associated floor sealant material off of at least one drug compartment during operation.

52. (Original) An inhaler according to Claim 51, wherein the dry powder package comprises:

a unitary dry powder package body comprising opposing top and bottom primary surfaces with a plurality of spaced apart wells having a depth formed therein, a respective well defining at least a portion of a respective drug compartment; and

a detachable floor sealant material extending across each drug compartment and sealably attached to the bottom primary surface of the dry powder package body to capture the dry powder in a respective drug compartment, wherein the tabs are configured as generally downwardly extending spaced apart tabs attached to an outermost edge portion of a portion of the floor sealant material proximate at least one drug compartment.

53. (Original) An inhaler according to Claim 51, further comprising an elongate inhalation drug flow path chamber and a vibrator disposed in the inhaler housing body in communication with the inhalation drug flow path chamber.

Claim 54 (Canceled).

55. (Original) An inhaler according to Claim 51, wherein each tab member is operatively associated with a neighboring first and second drug compartment, and wherein the neighboring first and second drug compartments comprise a different meted drug.

56. (Original) An inhaler according to Claim 52, wherein the drug compartments are configured as pairs of drug compartments, each pair of drug compartments holding a different meted dry powder drug therein, a common sealant material segment defining the floor of each pair of compartments, the common sealant material segment operatively associated with a single tab, wherein, in operation, the hook member engages a single tab and the common sealant material segment is pulled off of the pair of compartments to release both drugs therein for generally concurrent release into the inhaler to thereby allow combination inhalation dry powder drug delivery in operative position in an inhaler.

57. (Original) An inhaler according to Claim 51, wherein the plurality of drug compartments is at least 60.

Claims 58-59 (Canceled).

60. (Original) An inhaler according to Claim 52, wherein the dry powder package body has a generally circular perimeter when viewed from the top or bottom, and wherein the plurality of drug compartments comprise a first plurality of circumferentially spaced apart drug compartments disposed about a substantially common first radius extending from a center of the package and a second plurality of circumferentially spaced apart drug compartments disposed about a second substantially common longer radius extending from the center, with pairs of drug compartments defined by one from the first radius and one from the second radius.

61. (Original) An inhaler according to Claim 60, wherein each pair of drug compartments are operatively associated with a common single tab.

62. (Original) An inhaler according to Claim 61, wherein the tab is a loop member.

63. (Original) An inhaler according to Claim 62, wherein the tab has a closed perimeter surrounding an aperture, and wherein, in operation, the hook member is configured to extend through the aperture and capture a lower portion of the tab.

64. (Original) An inhaler according to Claim 63, wherein the tab comprises an elastomeric material that has increased structural rigidity relative to that of the floor sealant material.

65. (Original) A method of operating an inhaler, comprising;

moving at least one drug compartment held on a dry powder package into a dispensing position above a dry powder entry window in an inhaler, the dry powder package having a plurality of sealed drug compartments, each having a meted amount of dry powder held captured therein above a releaseably attached floor sealant material;

engaging a tab extending generally downwardly from a portion of the floor sealant material;

pulling the tab to concurrently pull the floor sealant material off of at least one drug compartment;

releasing dry powder from the at least one drug compartment into a target inhalation flow path; and

vibrating the dry powder in the flow path.

Claims 66-74 (Canceled).

REMARKS

Applicant has canceled claims herein above without prejudice thereto in order to reduce fees due at filing. Applicant reserves the right to re-enter the claims during prosecution and/or to pursue in future continuation/divisional filings.

Respectfully submitted,

Julie H. Richardson
Registration No. 40,142

USPTO Customer No. 20792
Myers Bigel Sibley & Sajovec
Post Office Box 37428
Raleigh, North Carolina 27627
Telephone: 919/854-1400
Facsimile: 919/854-1401

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Rosa Lee Brinson
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